K071121

Biomatlante

TRIBONE 80™

SEP 11 2007

510(k) Summary

BIOMATLANTE
ZA DES IV NATIONS
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Contact: Laurence Letertre
Regulatory Affairs Manager

This summary was prepared on April 2nd, 2007

1. DEVICE IDENTIFICATION

Trade Name:	TRIBONE 80™
Common Name:	Resorbable bone substitute
Classification Name :	Resorbable calcium salt bone void filler device
Product Code :	MQV
Regulatory Status :	Class II
CFR Section :	888.3045

2. PREDICATE DEVICES

Product Code	Applicant	510(k) #	Product
MQV	Orthotec	K040514	EOVIA
MQV	Howmedica	K033258	Bone Save

3. DEVICE DESCRIPTION

TRIBONE 80™ is a bone graft substitute. TRIBONE 80™ is a microporous and macroporous biphasic calcium phosphate ceramic consisting of 20% Hydroxyapatite (HA) and 80% beta-Tricalcium Phosphate (ß-TCP). TRIBONE 80™ is available in granules, sticks and blocks.
TRIBONE 80™ may be used with physiological saline, patient's own serum, whole blood, or bone marrow aspirate (BMA). TRIBONE 80™ can also be mixed with autograft.
TRIBONE 80™ is provided sterile for single patient use.

4. INTENDED USE

TRIBONE 80™ is intended for use as a bone void filler for bony voids or gaps of the skeletal system (e.g. extremities, spine and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.
TRIBONE 80™ is a bone filler without initial mechanical properties. Therefore rigid fixation techniques may often be recommended.
When packed into a bony site, TRIBONE 80™ gradually resorbs and is replaced with bone during the healing process.

TRIBONE 80™ is to be used in association with adequate post-operative immobilization.

5. SUBSTANTIAL EQUIVALENCE INFORMATION

The principal component and intended use of TRIBONE 80™ is the same as previously cleared devices. TRIBONE 80™ and the predicate device are substantially equivalent in design, materials of construction and function.

The safety and effectiveness of TRIBONE 80™ presented in this submission is adequately supported by the substantial equivalence information, safety and performance data provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

BIOMATLANTE
% Ms. Adeline Filliâtre
Regulatory Affairs Manager
ZA DES IV NATIONS
5, rue Edouard Belin
-F-44360 VIGNEUX DE BRETAGNE
FRANCE

SEP 11 2007

Re: K071121
Trade/Device Name: TRIBONE 80™
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: June 19, 2007
Received: August 2, 2007

Dear Mr. Filliâtre:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

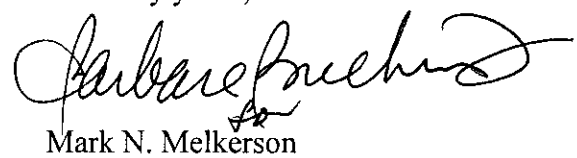
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Biomatlante

TRIBONE 80™

Indications for Use

510(k) Number (if known): K071121

Device Name: TRIBONE 80 ™

Indications for Use:

INDICATIONS

TRIBONE 80™ is intended for use as a bone void filler for bony voids or gaps of the skeletal system (e.g. extremities, spine and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.
TRIBONE 80™ is a bone filler without initial mechanical properties. Therefore rigid fixation techniques may often be recommended.
When packed into a bony site, TRIBONE 80™ gradually resorbs and is replaced with bone during the healing process.

TRIBONE 80™ is to be used in association with adequate post-operative immobilization.

TRIBONE 80™ is provided sterile for single patient use.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071121